REMARKS/ARGUMENTS

The present amendment is responsive to the Official Action mailed May 25, 2007. A petition for a two-month extension of the term for response to said Official Action, to and including October 25, 2007, is transmitted herewith.

The present amendment also makes of record the substance of the telephone interview between undersigned counsel and Examiner Peter Vrettakos on September 7, 2007. The Examiner's courtesy and cooperation in arranging for and conducting such telephone interview are greatly appreciated.

As discussed at the interview, independent claim 7 has been amended to incorporate the recitation formerly presented in claim 88, that the method is performed "without forcibly engaging a structure with the wall of the pulmonary vein." Also, in answer to the Examiner's question as to whether the recitation concerning "without forcibly engaging a structure with the wall of the pulmonary vein" also included the ostium of the vein, this recitation has been further clarified by adding the phrase "or the ostium" at the end of this recitation, which now forms the last paragraph of independent claim 7. As also discussed in the interview, claim 7 has been modified to state the recitation formerly set forth in claim 10, that the "chamber" referred to is "the left atrium" of the heart, *i.e.*, the chamber which communicates with the pulmonary veins. This recitation was formerly set forth in claim 10, and accordingly, has been deleted from claim 10.

Also, claim 7 has been amended to further clarify that the "region of the wall of the chamber" formerly referred to is a region of the wall of the atrium which is "disposed outside of the ostium of a pulmonary vein" (¶ (a)), and that the ablation is performed "without ablating within the pulmonary vein or the ostium." It is respectfully submitted that these changes merely clarify what was already expressed in claim 7; the specification

distinguishes the wall of the heart chamber or atrium from the pulmonary vein and the ostium, and the former recitation that "a region of the wall of the chamber" was to be ablated thus already conveyed the same information as is now set forth in the expanded recitations of claim paragraphs (a) and (c).

It is thus believed that the present amendment is one which can be properly entered under 37 C.F.R. § 1.116. Clearly, the incorporation of recitations from dependent claims ("atrium" and "without forcibly engaging") raise no new issues. It is also respectfully submitted that the mere clarification of the existing recitation (*e.g.*, by inserting "without ablating within the pulmonary vein or ostium") also raises no new issues. Moreover, clarification of the claim is believed to present the claim in better form for appeal.

As discussed during the interview, none of the references currently relied upon for rejection -- *Collins et al.*, U.S. Patent No. 6,837,866 ("*Collins*"); *Natale*, U.S. Patent No. 6,764,486 ("*Natale*"); and *Hassett et al.*, U.S. Patent No. 6,540,744 ("*Hassett*")[1] -- teach ablation of a region outside of the ostium. All of these references are directed to methods of ablation within the pulmonary vein or within the ostium, and do not ablate a region of the atrium wall disposed outside of the ostium. In the Official Action (p.3), and in the interview, the Examiner raised the point that the delineation between the pulmonary vein or the ostium and the chamber wall "is not distinct in normal physiology . . .," *i.e.*, that there is not normally a clear dividing line which would be obvious to a layman upon visual inspection. In the interview, counsel pointed out that the lack of a clear dividing line does not mean that the atrium wall is the same as the ostium or the vein.

[1] It is noted that *Hassett*, newly cited by the Examiner, appears to be identical to *Hassett et al.*, U.S. Patent No. 6,251,109, cited in the

Counsel drew the analogy of a city and its surrounding rural areas. When one is in a downtown region of a city, one is surrounded by office buildings and the like; when one is in the surrounding rural area, the landscape is full of farms and woods. The fact that there may be a gradual transition between the downtown and the rural through some suburbs which become progressively less urban and more rural does not mean that the rural area and the downtown city are indistinguishable. Likewise, the fact that there may be a gradual transition between the tissues of the pulmonary vein and ostium and the tissues of the heart wall does not mean that the heart wall is the same as the ostium or the pulmonary vein.

Also, as a matter of law, the fact that there may not be an abrupt boundary between one physical phenomenon and another does not make the phenomena indistinguishable or allow one to disregard limitations specifying that one of the phenomena is present. 35 U.S.C. § 112 requires no more than the use of language which is "as precise as the subject matter permits." *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985). The distinction between the "ostium" and the surrounding heart wall is as precise as the art, and its terminology, allow. Moreover, even if a recitation in the claim is regarded as vague, the PTO may not ignore such a limitation in evaluating patentability over the art:

> Rather than reject the claims as indefinite, the board chose to ignore the language it considered indefinite, and proceeded as though that language were not in the claims. The board said, in effect, that since we do not know what "incompatible" means, and the rest of the claim defines obvious subject matter, there is no basis for concluding unobviousness. This reasoning is incorrect. All words in a claim must be considered in judging the patentability of

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Information Disclosure Statement filed by applicants at the beginning of the case.

> that claim against the prior art. If no reasonably definite meaning can be ascribed to certain terms in the claim, the subject matter does not become obvious — the claim becomes indefinite.

In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Here, the distinction between ablation within the pulmonary vein or the ostium and ablation outside of the pulmonary vein and outside of the ostium are clear and would be recognized by one skilled in the art. *See, e.g.*, claim 1 of U.S. Patent No. 6,503,247, specifying that a lesion "is formed at least partially in an os of the pulmonary vein."

Collins explicitly teaches forming a lesion "in the blood vessel" by "expanding the braided conductive member at a selected location in the blood vessel so that the braided conductive member contacts a wall of the blood vessel and applying energy to the wall of the blood vessel via the braided conductive member to create a lesion in the blood vessel." (Col.3 ll.28-33.) The embodiment of Fig. 22, currently relied upon for rejection, is used by forming the "braided conductive member 28" into a disc and advancing the catheter 12 bearing the braided conductive member until the braided conductive member "makes contact with the ostium of the pulmonary vein 154" and applying "external pressure" on the catheter shaft so as to "achieve the desired level of contact of" the braided conductive member with "the ostium tissue." (Col.15 ll.13-23.) The preferred embodiments in *Collins* use conventional RF ablation, which requires a firm, low-impedance contact between the energy-applying device and the tissue. Although *Collins* mentions, broadly, various types of energy (*id.*, ll.24-25), the reference does not teach any way of configuring the device for effective non-contact application of energy. In short, *Collins* ablates within the ostium of the pulmonary vein or within the vein itself, and does so by forcibly engaging the ablation device with the tissue of the vein. *Collins* manifestly does not

teach a process as set forth in claim 7, in which the ablation device is disposed with the distal side of the device facing toward "a region of the wall of the atrium to be ablated," which region is disposed outside of the ostium of the pulmonary vein, and providing contrast medium and a portion of the image depicting "the contrast medium in at least a portion of the atrium so as to visualize the position of the ablation device relative to the atrium," as recited in paragraph (b) of the claim. Manifestly, *Collins* leads directly away from any method of ablation performed "without ablating within the pulmonary vein or the ostium" and performed "without forcibly engaging a structure with the wall of the pulmonary vein or the ostium, as recited in the terminal paragraphs of amended claim 7.

The Official Action suggests that it would have been obvious to modify *Collins* to arrive at the claimed method "as motivated by the normal desire of artisans to improve upon what is already known." However, the normal desire to improve what is taught by the prior art does not make it obvious to change the principle of operation of the prior art being modified. M.P.E.P. § 2143.02(VI) and the cases cited therein.

The Official Action raises the question of where the device of *Collins* would "lie in a similar patient with a smaller heart" and suggests that in a patient with a smaller heart, the device of *Collins* might "quite possibly" lie "in the wall of the heart chamber." It is respectfully submitted that this amounts to impermissible speculation as to how the person of ordinary skill in the art would apply *Collins*' teaching in procedures performed in patients of differing sizes. Again, *Collins* specifically teaches ablation within the pulmonary vein. The common sense application of *Collins*' teachings would be select a device which is suited to the anatomy of the particular patient being treated, so as to achieve the result sought by *Collins*; namely, ablation within the pulmonary vein. On this record,

there is nothing to suggest that a cardiac surgeon, the postulated person of ordinary skill in the art, would be so careless as to select the particular size of the device without regard to the anatomy of the patient. It is certainly not inherent in *Collins*' disclosure that the engagement of the *Collins*' device with the chamber wall rather than the ostium would occur. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 159 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted); M.P.E.P. § 2112(IV). The rejection under § 103 of claim 7 and the claims dependent thereon on *Collins* should be withdrawn.

The separate rejection on *Natale* also should be withdrawn. The Official Action correctly characterizes *Natale* as ablation "at the pulmonary vein," as shown in Fig. 2. Indeed, *Natale*'s scheme can only operate within the ostium or vein. *Natale* jams a balloon 4 carried on a catheter 2 to close off the "area of the orifice opening 5," *i.e.*, the os of the pulmonary vein; and then, after expanding the balloon and closing off the os, *Natale* draws back the "wire pull 14" so as to collapse the elongated ablation applicator 12 and force the ablation applicator 12 into the "annularly encircling spandrel area Z which is formed by the discharge orifice opening 5 and the front of the balloon 2." This assures that "the ablation applicator 12 fits tightly on the to be ablated tissues, so that tissue denaturation takes place highly efficiently." (Col.3 ll.45-55.) In short, *Natale* forcibly engages the ablation applicator with tissue within the ostium. *Natale* manifestly does not teach ablating without forcibly contacting tissue within the ostium, and does not teach ablation of the cardiac wall outside of the ostium. Further, the stated function of the

contrast medium in *Natale* is to detect "the correct position of the distal end 3 of the positioning catheter 2 inside the orifice opening 5" of the pulmonary vein before expanding the balloon and forcing the balloon forward to create the abutment. *Natale* does not teach injecting contrast medium while the ablation device is in its operative configuration.

The cases cited at page 4 of the Official Action concerning "changes in sequence of adding ingredients" all deal with situations where the sequence of adding ingredients or performing other process steps is manifestly irrelevant to the results achieved. None of these cases stand for the proposition that one can disregard the teachings of the prior art as to a specific order in which steps should be performed, which is manifestly significant to achieve the results sought by the prior art. *In re Gibson*, 39 F.2d 975, 5 U.S.P.Q. 230 (C.C.P.A. 1930) dealt with prior art which mixed three ingredients together, but did not specify the order of mixing or suggest that the order of mixing had any particular significance. In that particular circumstance, the C.C.P.A. held that selection of the order which gave the most satisfactory mixture was within the skill of the art. *Burhans*, 154 F.2d 690, 69 U.S.P.Q. 330 (C.C.P.A. 1946) dealt with a situation where multiple references not only suggested the individual steps, but also suggested the claimed order of steps: "In [the prior art references], the wheat germ is separately ground and treated to remove the rancid element in the germ, and the non-rancid germ is thereafter incorporated in aged flour . . . ." 69 U.S.P.Q. at 331. *Ruebin*, 128 U.S.P.Q. 440 (Pat. Off. Bd. of App. 1959), dealt with a situation in which the prior *Rueben* patent suggested no difference in result as to whether a metal layer or the impregnating thermoset material was added first.

In the years since, the Federal Circuit and its predecessor, the C.C.P.A., have repeatedly criticized the idea of trying to reduce the obviousness inquiry to some sort of general rules of patentability:

> The problem . . . with . . . "rules of patentability" (and the ever lengthening list of exceptions which they engender) is that they tend to becloud the ultimate legal issue -- obviousness -- and exalt the formal exercising of squeezing new factual situations into pre-established pigeon holes.

In re Yates, 663 F.2d 1054, 1056 n.4, 211 U.S.P.Q. 1149, 1152 n.4 (C.C.P.A. 1981). As the Federal Circuit ultimately held:

> The use of *per se* rules, while undoubtedly less laborious than a searching comparison of the claimed invention -- including all its limitations -- with the teachings of the prior art, flouts Section 103 and the fundamental case law applying it . . . but reliance on *per se* rules of obviousness is legally incorrect and must cease.

In re Ochiai, 37 U.S.P.Q.2d 1127, 1133 (Fed. Cir. 1995). This is really no more than commonsense application of the statute. Here, a "*per se*" rule that reversal of steps is ordinarily obvious would ignore the clear teaching in *Natale* as to why one should inject the contrast agent before bringing the structure to its expanded operative condition. *Natale* uses the contrast agent to confirm that the catheter is initially disposed within the desired orifice opening. Once the structure has been brought to its operative condition, it would be too late; the structure would have already been expanded into engagement with the wall of the wrong pulmonary vein, with consequent damage to the pulmonary vein. Moreover, at this stage, it would be impossible to inject fluid into the pulmonary vein and image the position of the balloon inside of the atrium; *Natale* teaches firm engagement of the balloon with the atrium surrounding the

ostium. Thus, step (b) of claim 7 would be impossible. In *Natale*'s teaching, reversing the order of steps would not be obvious; it would render *Natale*'s invention inoperable. For all of these reasons, the rejection of claim 7 on *Natale* alone should be withdrawn.

Hassett also teaches directly away from the method of claim 7 as amended. The operation of *Hassett*'s device is described at column 11, lines 14-57. After detecting "the source of the atrial premature contractions" within the pulmonary vein by means of a sensing electrode, the "inner balloon 22" is inflated so as to also inflate the outer balloon 20 within the ostium. (Fig. 2A.) The reference states that the balloons "must be sufficiently inflated to prevent completely the flow of blood through the pulmonary vein 14" (Fig. 2, 2A) "around the balloons (20, 22)," thus clearly teaching forcible engagement between the balloons and the vein wall or ostium. The reference thus leads directly away from any method meeting the recitations in the last three lines of claim 7. Moreover, the reference unquestionably directs the artisan to ablate tissue "at any location within the pulmonary vein (14) or in the os of the pulmonary vein (14)." (Col.11 ll.54-56.) *Hassett* manifestly teaches away from the recitation of claim 7, paragraph (c), of ablating "without ablating within the pulmonary vein or the ostium." Moreover, *Hassett*'s stated objective of completely blocking the pulmonary vein and injecting contrast medium into the pulmonary vein to confirm such complete blockage is antithetical to the idea of injecting the contrast medium so as to allow flow of contrast medium back into the atrium and obtain images depicting the contrast medium "in at least a portion of the atrium so as to visualize the position of the ablation device relative to the atrium."

Hassett, like other intra-vein ablation devices, is relatively unconcerned with the positioning of the ablation device "within the atrium"; *Hassett* depends upon the mechanical engagement of the device with the ostium to hold the device in position.

For the reasons set forth above, the rejection of claim 7 on *Hassett* should be withdrawn. The rejections of the dependent claims should be withdrawn for the same reasons as advanced above with respect to claim 7.

In the interview, during the discussion of the references now relied upon as teaching ablation within the pulmonary vein or ostium, counsel pointed out that commonly-owned U.S. Patent Publication 2002/0065512 ("the '512 Publication") taught ablation of the heart wall and did not have to ablate tissue within the ostium. In that discussion, counsel noted that even with a device of this nature, some of the early thinking had been directed to arrangements using mechanical location or engagement of the device as, for example, by mechanically engaging a tip on the ablation device with the ostium of the pulmonary vein, as shown, for example, in Figs. 11 and 14 of the '512 Publication. As discussed by counsel, the particular type of ablation device taught in the '512 Publication -- a unique reflector structure which provides a ring-like focused beam of ultrasound energy -- does not require abutment between the ablation device and the tissue to be ablated, and indeed it has been found that the irregular configuration of the heart normally makes complete abutment between an ablation device and the heart wall around an entire 360° ring difficult or impossible to achieve. As pointed out by counsel, the use of a contrast medium as presented claimed allows the physician to detect the orientation of the ablation device relative to the heart wall while the ablation device is

disposed in the atrium.

Although not discussed during the interview, the Examiner's attention is respectfully directed to paragraph 0072 of the '512 Publication, which discusses techniques for visualizing the position of the ablation device within the atrium. Those techniques, however, are not believed to be suggestive of the presently claimed techniques.

For the reasons set forth above, favorable reconsideration and allowance of all claims in the application as amended are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By_____

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